

Governor's Commission on Pharmacy Reimbursement

Final Report
March 30, 2006

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I Executive Summary

The Pharmacy Reimbursement Commission was appointed by Governor Doyle to recommend savings in an equivalent amount as his veto message instructions to reduce payment to pharmacies by \$29.5 million all funds (\$12.5 million GPR). The Governor instructed the Commission to find savings while compensating pharmacies fairly and protecting benefits to Wisconsin's most vulnerable residents.

This original savings target was based on Legislative Fiscal Bureau (LFB) projections that assumed a drug trend growth rate of about 12%. Using the most current DHFS projected drug trend growth rate of 4.4%, the impact of the Governor's veto instruction was re-estimated by DHFS and was revised to \$22.8 million all funds (\$9.6 million GPR).

The Governor appointed the following members to the Pharmacy Reimbursement Commission:

- § Sandy Anderson, Baraboo, President of St. Clare Hospital and Health Services
- § Shiva Bidar-Sielaff, Madison, Manager of Cross Cultural Care and Interpreter Services at UW Hospitals and Clinics
- § Deborah Captain, Abrams, Executive Director of Good Shepherd Services in Seymour
- § Gary Donaldson, Mountain, President and Owner, Nicolet Pharmacy in Lakewood
- § Patricia Finder-Stone, DePere, Consumer advocate and community activist
- § Kimberly Hodgkinson, New Berlin, Director of Finance at Aurora Health Care Ventures
- § Tyson Lang, Altoona, Pharmacy Manager of Colby Pharmacy in Whitehall
- § Douglas Lee, Marshfield, Medical Director of Pharmacy Services at Marshfield Clinic
- § Mark Moody (Chair), Madison, State Medicaid Director at Department of Health and Family Services
- § James Riordan, Madison, President and CEO of WPS Health Insurance
- § Nicholas Sharrow, Columbus, President of Sharrow Drugs, Inc. in Columbus and Owner, Zimbric Pharmacy in Waterloo
- § Bruce Weiss, Fox Point, President and CEO of Managed Health Services, Inc.

The Commission met four times between November 2005 and March 2006. At its meetings, the Commission heard testimony from a variety of sources about the cost of dispensing; the cost at which pharmacies acquire brand and generic drugs; the potential impact of the implementation of the Governor's veto instructions; and opportunities to save money and improve outcomes without cutting payment to pharmacies.

The Commissioners are in broad agreement that retail pharmacists are important partners in controlling both prescription drug costs and overall health care costs, and that Medicaid payment practices should encourage that partnership more effectively than current practices or the payment reductions in the Governor's veto instructions.

The Commission's report contains reports prepared by subcommittees of the Commission on a series of topics.

1. Commissioners Hodgkinson, Riordan and Sharrow prepared a report on the economic impact of the proposed vetoes. Commissioners are concerned that the payment reductions would jeopardize the economic viability of some independent pharmacies and that others would withdraw from the Medicaid program. Both outcomes could make it more difficult for consumers, particularly in rural areas, to get care and that could lead to higher MA costs for transportation and other services.

2. Commissioner Bidar-Sielaff prepared a set of recommendations regarding modifications to Wisconsin's Pharmaceutical Care (PC) program, which allows pharmacists to bill for professional services above and beyond routine dispensing. Her report recommends simplifying the administration and claiming for pharmacists; increasing fees; and expanding the services for which PC can be claimed.
3. Commissioners Lee, Anderson and Weiss prepared a report on the potential quality and safety issues arising from the practice of dispensing free samples by physicians and recommended that the Department establish policies governing this practice.

Pharmacy Cost Management Recommendations

The Commission as a whole reached broad consensus on the following measures to save money without harming patient care or outcomes:

Recommendation	Estimated Savings This Biennium (15 months)
a) Expand preferred drug list	
§ Without Atypical Antipsychotics	\$8.5 million
§ Add Atypical Antipsychotics	\$4.0 million
b) Dose Consolidation	\$2.1 million
c) Tablet Splitting	\$4.3 million
d) Quantity Limits	\$1.0 million
e) 100-Day Supply	\$3.3 million
f) Crossover Rebates	\$1.0 million
g) Medication Review by Pharmacists	\$1.9 million
h) Pharmaceutical Care Payment for Switch to Generic	\$0.7 million
Total Estimated Savings This Biennium	\$26.8 million

The cumulative savings per year (12 month period) at full implementation of these recommendations are estimated to be \$24.5 million.

Cost of Dispensing and Drug Acquisition Costs

The Commission received testimony from Dr. Kreling, of the University of Wisconsin, on his findings on the costs of dispensing prescription drugs. He concludes that, in 2006, on average it cost a pharmacy in Wisconsin \$9.50 to fill a prescription above and beyond the costs to acquire the drugs being dispensed.

Medicaid pays a dispensing fee of \$4.38 per prescription plus an amount for the estimated cost of obtaining the drugs.

There was agreement that the Department's payment for generic drugs is, on average, very close to the pharmacies' actual costs of acquiring them and there is very little gross margin on generic drugs to make up the difference between the \$4.38 MA dispensing fee and the \$9.50 average cost of dispensing.

The Commission was not, however, able to reach agreement on what it costs pharmacies to acquire the brand drugs they are dispensing and, therefore, what their average gross margin is for brand drugs. The generally accepted range for brand drug acquisition costs is between 15% and 22% less than AWP (a broadly available listing of "average wholesale price") but individual

pharmacies' costs do vary based on a number of factors. Since Wisconsin Medicaid pays AWP minus 13% for MA and BadgerCare, and AWP minus 8% for SeniorCare, plus the \$4.38 dispensing fee, net payment to pharmacists is very sensitive to what their actual acquisition costs are for the drugs they dispense.

The average drug cost for brand medications paid for by Wisconsin Medicaid was approximately \$120 in 2005. At that average price, the average gross margin on brand drugs before dispensing fee would range from a high of \$16.80 to a low of \$2.40 depending on the average discount from AWP that an individual pharmacy is able to achieve.

Because of the great range in margin on brand drugs, the Commission did not arrive at a unanimous agreement on payment to pharmacies. The Commission did, however, adopt the following recommendations by a vote of 8 to 3:

Reimbursement Recommendations	Estimated Cost This Biennium (6 months)
§ Reduce payment for brand name drugs to AWP-15%, effective January 1, 2007.	(\$3.9 million)
§ Eliminate the 5% premium for SeniorCare (brand and generic), effective January 1, 2007.	(\$4.9 million)
§ Increase generic dispensing fee to \$9.88, effective January 1, 2007.	\$14.7 million
§ Maintain current pharmacy reimbursement rates for brand name drugs through December 31, 2006.	No impact
§ Maintain the current brand dispensing fee.	No impact
§ Maintain current DHFS policy of an average mark-up of 10% on generic drugs.	No impact
Total Estimated Cost This biennium	\$5.9 million

The cumulative costs per year (12 month period) of these recommendations are estimated to be \$11.9 million.

Cumulative Financial Impact of Commission Recommendations

The combined fiscal effect attributable to the pharmacy cost management recommendations for 15 months and the reimbursement increase recommendations for 6 months is a net savings this biennium of \$20.9 million, just short of the level sought by the Governor. The combined savings this biennium reflect a later start date for the reimbursement changes than for the cost containment measures.

Fulfilling the Governor's savings target on an annual basis going forward would require cumulative savings of \$15 million per year. The Commission's recommendations deliver a net \$12.6 million in annual savings, which is \$2.4 million short of the Governor's annual target. Nonetheless, the combined recommendations of the Commission will produce nearly comparable total savings without a net reduction in pharmacy margins.

II Introduction and Commission Charge

The biennial budget, 2005 Act 25, as vetoed by the Governor reduces Medicaid pharmacy reimbursement for brand name drugs to the Average Wholesale Price (AWP) minus 16% and reduces the dispensing fee for all prescriptions by \$0.50, from \$4.38 to \$3.88. These changes were estimated to decrease expenditures over the biennium by \$29.5 million all funds (\$12.5 million GPR). This original fiscal impact was based on Legislative Fiscal Bureau (LFB) projections that assumed a drug trend growth rate of about 12%. Using the most current DHFS projected drug trend growth rate of 4.4%, the impact of the Governor's veto instruction was revised to \$22.8 million all funds (\$9.6 million GPR).

The proposed reimbursement changes were suspended while the Pharmacy Reimbursement Commission appointed by the Governor was convened. The Governor has charged the Commission with finding alternatives that achieve comparable biennial savings. The Governor, in a press release announcing the formation of the Commission, indicated a commitment to providing pharmacies with a fair payment rate while promoting cost efficiency that preserves Medicaid benefits for Wisconsin's most vulnerable residents. Specifically, the language of the October 27, 2005 press release was as follows: "The Governor remains committed to providing pharmacies with a fair rate while protecting benefits for our most vulnerable residents."

Department of Administration Secretary Mark Marotta, in a September 19, 2005 letter to DHFS Secretary Helene Nelson, provided this charge to the Commission:

The Governor will appoint the Commission to develop recommendations to achieve biennial savings comparable to the amounts saved through the pharmacy vetoes. To achieve these savings, the Commission should recommend changes to the state's pharmacy reimbursement system for the MA, BadgerCare and SeniorCare programs. These recommendations could include: implementing an alternative methodology for setting the acquisition price for name brand and generic drugs, using a tiered reimbursement system, and/or changes to the dispensing fee to reflect the level of therapeutic review.

The Governor remains committed to providing reimbursement levels that represent a fair price and maximize efficiency in delivering health care benefits to our most vulnerable residents. Working with health care industry representatives to reform and improve the reimbursement system for pharmacy benefits will enable us to reduce costs while maintaining vital benefits.

III Principles and Goals

In meeting this charge, the Commission identified five broad principles and goals that served to guide its discussions and recommendations:

- 1. The goals of Medicaid pricing and policy should be to lower overall expenditures for drugs while maintaining or improving health outcomes for consumers.*
- 2. Payments to pharmacies should be fair and recognize that pharmacists are important partners in the State's efforts to control costs and achieve effective therapeutic outcomes. Specific outcomes to be encouraged should include continuing to increase utilization of generics and continue to transition consumers to more cost effective dosages or medications.*
- 3. Payment methods should require pharmacists to obtain drugs at very competitive prices.*
- 4. Payment to pharmacists should cover the reasonable operational cost of the services they provide, with ingredient costs reimbursed as close to actual costs as can reasonably be determined.*
- 5. Medicaid policies and procedures should be designed to get the right drug to the consumer promptly, with a minimum of administrative costs and disruption for pharmacists and prescribers.*

Throughout its deliberations and decision-making process, the Commission sought to balance the interests of various stakeholders, including pharmacists, Medicaid recipients and taxpayers. It is in the interest of pharmacies to be provided with sufficient reimbursement to cover their costs of doing business, i.e., the cost of the drug (ingredient cost), and the costs of dispensing and some profit margin. It is in the interest of recipients to have convenient local access to quality pharmacy services that include sufficient time for the pharmacist to provide education and consultation. It is in the interest of Wisconsin taxpayers that the Medicaid program net prescription drug costs are the lowest price possible consistent with the objectives above.

IV Economic Impact of Veto Instructions

The Commission discussed at length the potential impact of implementing the Governor's veto instructions, which will reduce reimbursement to pharmacies by increasing the discount to brand name drug payments and by reducing the dispensing fee Wisconsin Medicaid will pay to pharmacies for both brand and generic drugs. Three of the Commissioners produced a report on their assessment of the economic impact of the Governor's veto, if allowed to stand.

Several Commissioners expressed concern that the Governor's recommendation to reduce reimbursement for brand name drugs and to reduce dispensing fees for brand name and generic drugs would have a negative impact on Medicaid, BadgerCare, SeniorCare and HIRSP recipients' access to pharmacy services. These concerns are elucidated in the economic analysis report, which follows.

Wisconsin Pharmacy Reimbursement Commission

Economic Impact Analysis

Kimberly Hodgkinson, Commissioner
Jim Riordan, Commissioner
Nick Sharrow, Commissioner

Background

As part of the 2005-2007 State of Wisconsin Budget, Pharmacy Reimbursement for Medical Assistance, BadgerCare and SeniorCare was to be reduced as follows:

(1) Rates for Brand Name Prescription Drugs

Current Rate	AWP – 13%
Proposed Rate	AWP – 16%

(2) Dispensing Fees for both Brand and Generic Drugs

Current Rates	\$4.38
Proposed Rate	\$3.88

The Joint Finance Committee restored the rates to their current levels, and the Governor subsequently vetoed these restorations to the Budget, and reinstated these reductions to the Budget. These proposed rates were scheduled for implementation on September 1, 2005 but were delayed until February 1, 2006 in order for other options to be pursued by a Pharmacy Reimbursement Commission.

It should also be noted that factored into the Budget was a move of 52% of the drug spend due to the implementation of the Medicare Prescription Drug Plan (Part D) and the transition of Medicare-Medicaid dual eligible patients to Part D. The State will incur a claw-back that will require a graduated funding of these patients back to the federal level.

Financial Review

The total biennium reduction in reimbursement to pharmacies based upon the current changes in the Budget will be \$29.2 million. These reductions, when combined with the reimbursement rates for generic drugs, will result in Wisconsin having the lowest pharmacy reimbursement rates in the Midwest and perhaps the nation.

The following outlines each provision.

1. Reduced Rates for Brand Name Prescription Drugs

The average cost for a brand name prescription drug to the State is \$120.12 per prescription. A 3% reduction in payment to pharmacies will result in a biennium reduction of reimbursement to pharmacies of \$22.2 million based upon an effective date of September 1, 2005.

Average Cost per Prescription	\$120.12
3% Reduction per Prescription	\$3.60
Average Biennium Cost Reduction	\$22.2 million*

2. Reduced Dispensing Fees for both Brand and Generic Drugs

A reduction of \$0.50 per prescription has a total biennium impact of \$7.0 million.*

Economic Impacts

The following is a list of economic impacts that will result from the proposed reimbursement rates:

1. Limited or No Access to Services

This reduced reimbursement has many pharmacies considering whether they are able to continue to serve this population. In most cases the reimbursement levels are substantially less than a pharmacy's cost to dispense a prescription. Pharmacies may completely discontinue servicing these patients or limit the sites that service these patients.

Rural pharmacies are most likely to opt-out of the State program altogether. Large corporations and healthcare-based pharmacy providers are likely to limit access by site.

2. Reduced Quality of Services

Pharmaceutical services are meant to provide a patient with services to assist and maintain their health. Without adequate reimbursement, pharmacy staff will be reduced and less time will be available to provide the individual attention required for many of these patients served by the State programs. Reduced staff also increases the likelihood of medication errors, which in turn can result in increased costs for the State programs.

3. Increased Costs to the State

If pharmacies close or limit access to services, the State will have to cover the travel expenses for any patient who does not have reasonable access to a pharmacy. In addition, this may result in higher medical expenses as patients are not able to access pharmacy services and then look to alternative sites for care, such as emergency rooms and urgent care sites.

* Subsequently reestimated by Department staff based on more recent data.

This would not only happen in rural areas, but in more populated areas where patients are not able to access pharmacy services because they are not located close to a bus line.

4. Decrease in Economic Activity for the State

It is estimated that the decrease in economic activity for the State would be \$84.1 million and a loss of approximately 957 jobs statewide.

This will enhance the stress of working in the pharmacy services industry and continue to put a strain on the recruitment and retention of pharmacist and pharmacy staff. Pharmacies may also reduce employment benefits to those staff remaining in an effort to address the financial losses that would occur from the program reimbursement reductions.

5. Impact on Other Pharmacy Contracts

The proposed reimbursement change has a domino effect to other reimbursement contracts that are directly linked to the State Medical Assistance reimbursement rates. Such contracts include services to nursing homes, assisted living facilities, and county services. This will further increase the negative financial impact to pharmacies.

In addition, this may lead other pharmacy benefit services to seek lower reimbursements. Current commercial contracts are competitive on brand drug reimbursement, but provide for adequate reimbursement for generic drugs.

Recommended Action Regarding the Economic Impact

The State cannot continue to reduce reimbursement to the pharmacies as a solution to its budget deficits. These businesses support the economy of Wisconsin and should be treated fairly with respect to the services they provide and the cost to provide such services. Further, a review of Medicaid and SeniorCare program data illustrates that pharmacy provider reimbursement rates have not led to increases in program costs. Program costs have risen due to increases in prescription drug costs and increased utilization of the program by recipients.

The proposed pharmacy reimbursement reductions for the Medicaid, BadgerCare and SeniorCare programs should not be implemented as identified above. The economic impact reaches far and may limit, if not eliminate, access for the vulnerable population these programs are meant to serve.

Pharmacy reimbursement should be restructured so that it provides fair reimbursement for both brand and generic drugs, as well as an appropriate dispensing fee. These enhanced reimbursements should be coupled with new and/or modified policies for the administration of the Medical Assistance, BadgerCare and SeniorCare programs.

In addition to the report above, the Commissioners also noted that pharmacists are already adversely impacted by Medicare Part D in the following ways:

- € Conversion of 108,000 Medicaid dual eligibles to Part D and the lower fees paid by the Part D plans.
- € Serious cash flow concerns caused by significant Part D start-up problems.

In addition, the increase in Medicaid's generic fill rate from 52% to 62% has reduced pharmacy gross margin from about \$17 to \$4.75 for each prescription converted; far below pharmacies average cost to dispense of \$9.50.

Commissioners predict that the cumulative effect of these changes and that the Governor's veto will cause an unknown number of pharmacies to either close or stop serving Medicaid, BadgerCare and SeniorCare clients. This would be more likely to happen in isolated, rural communities, leaving consumers with no local services.

DHCF staff prepared an analysis that projects the revenue reduction for each participating pharmacy, which is attached in Appendix 1.

V Policy Initiatives and Program Improvements

As directed by the Governor, the Commission spent significant time discussing options for pharmacy program savings achieved through means other than reductions in reimbursement rates to pharmacies.

Two Commission subcommittees specifically submitted reports looking at policy changes.

Pharmaceutical Care Program

The Commission considered several changes to the Pharmaceutical Care (PC) program. Pharmaceutical Care promotes a patient-centered, outcomes-oriented practice of pharmacy. Its purpose is to maximize the effectiveness of medications for patients through intervention by the pharmacist. The enhanced dispensing fee that accompanies these services is also designed to achieve net savings (payments to pharmacies are more than offset by savings from efficient medication management). Wisconsin Medicaid currently pays providers for Pharmaceutical Care between \$9.45 - \$40.11 per service.

Use of this benefit has been limited. In SFY 2005, a total of \$164,000 was claimed for Pharmaceutical Care. Commissioners heard testimony that billing for pharmaceutical care is less than optimal because of the complexity of the billing procedures. The Pharmaceutical Care report, which follows, outlines these issues in greater detail and proposes a series of recommendations to streamline and improve Pharmaceutical Care.

The Commission reached broad consensus with the four recommendations contained in Commissioner Bidar-Sielaff's report. Some of the specific policy options recommended by the Commission are based upon use of the pharmaceutical care program. The Commission further recommends that the Department implement the simplification and enhancement called for in the following report to ensure optimal use of the program and to maximize program quality and savings.

Wisconsin Pharmacy Reimbursement Commission

Pharmaceutical Care Program Recommendations

Shiva Bidar-Sielaff, Commissioner

At the 12/15/05 meeting of the Commission I volunteered to review the pharmaceutical care program offered by the State and to make recommendations for the Commission to consider relative to improving its design and use. Indeed, during that same meeting, we ranked pharmacy care management and coordination (page 7 of 12/15/05 meeting minutes) as one of our top recommendations for a cost effective pharmacy reimbursement system. In addition to reviewing the published material on the program, I solicited the input of practicing pharmacists and the Pharmacy Society of Wisconsin in my review. I respectfully recommend that the Commission consider and propose each of the recommendations below.

Background

Under 1995 Wisconsin Act 27, the Department of Health and Family Services (DHFS) was required to develop an incentive-based pharmacy payment system that pays for Pharmaceutical Care (PC) services. The term “pharmaceutical care” was defined formally in 1990 and refers to the practice of taking responsibility for optimizing all of a patient’s drug therapy in order to achieve better patient outcomes and improve the quality of each patient’s life. Pharmaceutical Care is provided by the identification, resolution and prevention of drug therapy problems by pharmacist intervention. The Wisconsin Medicaid Pharmaceutical Care Program (WMPCP) provides pharmacists with an enhanced dispensing fee for PC services provided to Medicaid fee-for-service and Senior Care recipients. This enhanced fee was intended to reimburse pharmacists for services provided above and beyond the standard dispensing and counseling on a prescription drug product.

Though an important part of the Medicaid and SeniorCare pharmacy benefit, PC billing has not been widely adopted and utilized by Wisconsin pharmacists to the extent that was intended. Barriers to the use of the program most often cited include: inadequate payment levels, complexity of billing, lack of uniformity among pharmaceutical care programs, and insufficient support among pharmacy managers. By increasing payment for services provided and lessening the billing complexity, it is likely that pharmacy managers will increase their support of the program and encourage its use by pharmacists.

The WMPCP enables increased quality of care to be provided to Wisconsin Medicaid and Senior Care patients, and decreases medication and other related health care costs to the State of Wisconsin. Pharmacists are well-suited to provide these services to patients and the State should update the WMPCP to enhance its use and improve its value.

Recommended Changes to the Current WMPCP

1. Separate the enhanced dispensing fee from the traditional dispensing fee.

Decoupling the enhanced WMPCP dispensing fee from the traditional dispensing fee would allow pharmacists to more conveniently and consistently bill for services provided. Currently, many pharmacy software systems require reversal of a drug product claim in order to bill for services provided while others require the claim to be voided and reentered in order to bill for PC services. The amount of time required to successfully carry out these two scenarios is often cost prohibitive. In addition, if the claim is denied, the pharmacy loses reimbursement for the enhanced dispensing fee in addition to the traditional dispensing fee. The provision of a billing method by DHFS that separates reimbursement for the drug product from reimbursement for pharmaceutical care services provided would increase the use of the WMPCP by pharmacists.

2. Increase WMPCP payment levels.

Current payment levels for pharmaceutical care services are insufficient and do not provide the necessary financial incentive for pharmacists to use the WMPCP. Recommended PC reimbursement changes include increasing

- Ø product-oriented interventions to \$30 per intervention. This will bring the reimbursement to a similar level than commercial payors.
- Ø service-oriented interventions to \$2-3 per minute. A study prepared for the American Pharmacists Association by The Lewin Group and published in May 2005 (*Medication Therapy Management Services: A Critical Review*) indicates that to be sustainable “a payment system must provide unit payments [...] to cover total costs (approximately \$2.00 to \$3.00 per minute, according to industry estimates.)”

3. Simplify the WMPCP billing process.

Simplification of the current billing process and reimbursement structure would allow pharmacists to more feasibly bill for PC services. The current WMPCP utilizes a myriad of codes that must match in order for payment to be received. Also, the list of pharmaceutical care interventions that is covered is lengthy. The recommendation is to create a shorter list of WMPCP codes based on the most frequent PC interventions.

4. Additional clinical service considerations for WMPCP.

The scope of the current WMPCP clinical service offerings should be reevaluated and updated. Examples of additional clinical services to be considered include: use of tablet-splitting programs, medication therapy management services such as comprehensive and targeted medication therapy reviews, post hospital/skilled care facility discharge medication reconciliation, blood pressure and glucometer instruction and management, smoking cessation instruction, and pharmacist-administered immunizations.

DHFS should work closely with the Pharmacy Society of Wisconsin and its members who have used the WMPCP program to define and implement specific changes to the current WMPCP based on the four previously mentioned recommendations.

Recommended Action Regarding Further MTM Quality Improvement

The Pharmacy Society of Wisconsin has expressed its interest in the development of a statewide standard among health plans for the provision of medication therapy management and pharmaceutical care services. DHFS should provide leadership and active participation toward the success of this effort, utilizing its experience with the WMPCP.

The Commission has responded to this report by recommending several policy options outlined later in this report that utilize the Pharmaceutical Care incentives to initiate dose consolidation and tablet splitting programs, as well as medication reviews and generic conversions.

The Commission has further recommended, as a quality improvement strategy, simplifying Pharmaceutical Care billing. This effort will require time to develop new billing procedures and will consider issues of rates as the structure is reformulated.

Medication Sampling

In a third report, Commissioners Anderson, Lee and Weiss explored management strategies to reduce sampling practices that compromise patient safety and the State's Preferred Drug List by stabilizing patients on a brand medication via sampling. As a companion to the report, the Sampling Medication subgroup also submitted an article on the subject from *JAMA*, which is attached as Appendix 2.

The Commission expressed broad support for changes in medication sampling policies, although time constraints did not allow us to discuss the recommendations in detail. The Commission recommends that this issue be further reviewed by DHFS staff.

Wisconsin Pharmacy Reimbursement Commission

Sample Medication Subgroup Recommendations

Douglas Lee, M.D., Commissioner
Sandy Anderson, Commissioner
Bruce Weiss, M.D., M.P.H., Commissioner

A sub-group of Commissioners were asked to review the potential quality, safety and financial impact that drug samples dispensed by practitioners have on the Medicaid, BadgerCare and Senior Care participants and to make recommendations to address these issues.

Background

Regulatory

Both Federal and State statute require that specific records be maintained in the distribution and dispensing of prescription medication in order to closely track distribution of medications, in case of contamination or irregularities during manufacturing or storage. Federal law (21 CFR 203.38) requires that manufacturers keep detail records of which sample medications are distributed to which physician/provider offices. These records are to include control or lot numbers in such a manner to allow for tracking of the medication to the licensed practitioner, in cases of recall or adverse reactions.

State law (Med 17.05) requires that a practitioner record in the patient's record each prescription drug dispensed. This recording of the medications should include quantity, lot numbers and expiration date for the purpose of identification of patients at potential risk of adverse effects due to a recall of medications. Rarely is the required record keeping actually documented in patient records, creating a potential issue of patient safety.

Safety/Quality

Recent advances in on-line adjudication of prescription medications allow for real-time drug utilization reviews for possible adverse drug-drug interactions, excessive dosage or other potential adverse effects. Dispensing of samples bypasses the claims system and therefore limits critical drug utilization data and circumvents these patient safeguards.

An additional benefit of on-line adjudication of prescription medications is the opportunity to implement automated prior authorization step edits, based on prior drug utilization. Automatic prior authorizations (PA) can be given based on pre-determined protocols established by the P&T Committee based on a patient's prior drug utilization history. This process is also circumvented by the dispensing of samples.

Recommendations:

- 1. DHFS not approve PA requests for non-Preferred Drug Listing (PDL) medications based on the stated reason that a patient/recipient has been stabilized on a non-PDL medication provided as a “sample”. These requests should be denied and the provider should be directed to prescribe a PDL medication.**
 - a. Initiating a patient’s treatment with non-PDL drug samples bypasses current patient safeguards for drug-drug interactions and circumvents the State’s prior authorization process. By excluding stabilization on samples as a valid reason for approval of non-PDL, the State will require that all prescriptions are adjudicated through the on-line system which records the utilization and provides numerous patient safeguards.
 - b. By disallowing “stabilization on samples” as an acceptable reason for authorizing continuation of a non-PDL medication, the State should realize lower costs through an increase of generic and PDL medications.
- 2. DHFS should require that physicians provide, State-required documentation regarding the dispensing of samples for all PA requests involving drug samples.**
 - a. This policy will assure compliance and awareness of current State requirements regarding proper documentation involved in dispensing sample drugs.
- 3. For any PA request based on failure of a non-preferred agent, which was provided as a sample, the prescriber must provide on the PA request the state-required documentation regarding the dispensing of samples. This documents compliance with State statute and that a sample was tried and failed.**
 - a. Prescribers will need to be reminded that all medications being dispensed to patients, including Medicaid, BadgerCare and SeniorCare enrollees, are subject to State dispensing and documentation requirements to assure patient safety and accuracy of the medical record.
 - b. Such documentations for samples should be placed in the patient record and include the recording of the medication, strength dispensed, frequency of dosing, number of units, lot number and expiration date.
 - c. DHFS should evaluate the impact these changes have on the number of PA requests received and approved.
- 4. DHFS should initiate meetings with other stakeholders to discuss opportunities and partnerships to address the sampling issue and any other issues that impact on quality of drug selection. Such areas of opportunity may include:**
 - a. Analysis of the costs borne by medical practices by dispensing sample drugs.
 - b. Education of prescribers about the regulatory requirements and risks imposed by sampling.

- c. Identifying parties with common interests and abilities to address common concerns.
- d. Parties who might have common interests in this may include the State Medical Society, Pharmacy Society of Wisconsin, Wisconsin Association of Health Plans, other payers, University of Wisconsin researchers and any state organizations interested in improving patient safety and reducing healthcare costs.

The sampling practices report made specific recommendations for using the prior authorization process to discourage the practice of stabilizing patients on a brand medication using samples. The Commission encourages the Department's Prior Authorization Advisory Committee to review and consider these recommendations.

Pharmacy Cost Management Recommendations

The Commission also recommends the following savings initiatives be initiated by the Department to promote cost efficiency / cost savings while encouraging appropriate utilization and maintaining quality care. Savings estimates provided below have been calculated by DHFS staff for the remainder of the biennium, and are All Funds.

Preferred Drug List – The Commission supports the continued implementation of the Preferred Drug List, and supports consideration of the atypical antipsychotics for inclusion on the PDL. Estimated savings: \$12.5 million (\$8.5 without atypical antipsychotics).

Dose Consolidation – For appropriate classes, dispense one larger dose per day instead of two smaller doses. Estimated savings: \$2.1 million, net of a \$10 per service pharmaceutical care payment.

Tablet Splitting – Split tablets for drugs with relatively “flat” pricing, (the cost difference between strengths is minimal), so that splitting the drug with twice the strength reduces the cost of the drug by 50%. Estimated savings: \$4.3 million, net of a \$10 per service pharmaceutical care payment.

Quantity Limits – Reduce allowable days supply per month to less than the standard 30 days supply for selected drugs, as clinically appropriate. Estimated savings: \$1.0 million.

100 day supply – Allows a recipient to obtain larger quantities of select maintenance drugs at a time, thereby reducing the copayment for the recipient and decreasing the professional fees paid for by the program. Estimated savings: \$3.3 million.

Crossover Rebates – Claim manufacturer rebates on Medicare crossover claims by compiling a 5-year claims history for single source J codes. Estimated savings: \$1.0 million.

Medication Review by Pharmacists – Introduce a medication review program for recipients who are receiving more than 10 prescriptions per month. Pharmacies receive a \$25 pharmaceutical care fee for each review completed. Estimated savings: \$1.9 million (assumes 5% of prescriptions in excess of 10 per month can be eliminated, with each prescription valued at \$65 and assuming a \$25 pharmaceutical care payment offset).

Pharmaceutical Care Payment for Shift to Generic Products – Pay pharmacies a Pharmaceutical Care fee between \$10 and \$15 when they are successful in converting an *existing* prescription that has been filled in the past as a brand to a generic or PDL preferred prescription. Estimated savings: \$0.7 million. (Assumes 8,500 to 9,000 prescriptions will be converted at an average net savings of \$80 per prescription, including the Pharmaceutical Care payment).

Non-Cost Related Recommendations

The Commission is also making the following quality improvement recommendations that do not generate immediate cost savings, but are intended to improve the overall quality of administration and recipient care services. As already discussed, two of these three items (Pharmaceutical Care and Sampling) originate from specific reports submitted by Commission subcommittees. They are included earlier in the report.

- § **Simplify Pharmaceutical Care Billing** – Create an automated billing mechanism for Pharmaceutical Care services to replace complicated hand-billing procedures pharmacies must currently follow to generate fees.
- § **Do Not Allow Samples to Qualify for PA** – Create prior authorization criteria that exclude patient stabilization on brand samples as a reason for allowing access to non-preferred brand medications.
- § **Use Technology to Simplify and Streamline PA Review Process** – This strategy involves reviewing ways to use web-based prior authorization and e-prescribing as additional tools available to minimize pharmacy workload related to PA requests that are not accurately submitted by prescribers.

Pharmacy Society of Wisconsin Recommendations

The Pharmacy Society of Wisconsin (PSW) submitted for Commission consideration a list of items intended to recommend a payment formula and to offer cost savings measures to help offset the associated costs. These items are attached in Appendix 3. Most of these items have already been addressed in the recommendations outlined in this paper. Two additional items not addressed in this paper are to reform the brand medically necessary prior authorization approval system and develop a statewide standard on medication management. These items are recommended for referral as appropriate to DHFS' PA Committee and/or DUR Board.

VI Current Prescription Drug Payment Formula

Wisconsin Medicaid, like virtually all payers, pays pharmacists for dispensing medications to consumers in two parts:

- § A dispensing fee for professional services (including ordering, inventory, filling, billing and counseling the consumer). In the case of Wisconsin Medicaid, BadgerCare and SeniorCare, these services often include obtaining information required for prior authorization of drugs not on the preferred drug list (PDL) or working with the prescribers to prescribe a preferred drug.
- § Payment for the medications (ingredients) plus a small ingredient markup to assure costs are covered and to account for the fact that the cost of dispensing is greater than the dispensing fee that is paid.

Generally, the dispensing fee is a uniform amount per prescription. The ingredient costs are the payer's allowance for the pharmacists' cost of acquiring the drugs. As such, total reimbursement to pharmacies is expressed as: Total reimbursement = ingredient allowance + dispensing fee. Medicaid and other payers are also beginning to provide payment for services in addition to routine dispensing. These services relate to pharmacist involvement in the selection and use of preferred products and in the management of more complex medication regimens.

Estimating Ingredient Costs

Pharmacists' ingredient acquisition costs are not known to payers for a variety of reasons. Pharmacies purchase from multiple sources under differing terms so that even a single pharmacy may be sourcing a single drug at multiple prices.

Because acquisition costs vary among pharmacies and are not specifically known, they are estimated. All prescription drug payers, including Wisconsin Medicaid, BadgerCare and SeniorCare, must estimate pharmacies' actual acquisition cost (AAC) for most drugs. The estimated acquisition cost or EAC is any given payer's allowance for the price generally and currently paid by pharmacies for a drug marketed in the dosages and drug forms being dispensed. Most payers have one method for estimating the acquisition costs for multiple source drugs (generics) and a different method for single source, innovator products (brand names).

Generic Drug Ingredient Reimbursement

A reimbursement method referred to as Maximum Allowed Cost (MAC) is used by Wisconsin Medicaid to set reimbursement rates for generic products that are readily available from multiple manufacturers. Under MAC, the Wisconsin Medicaid programs pay pharmacies an amount it determines to be, on average, 10% above the lowest price available in the market for that drug/dose combination. This becomes the uniform amount paid regardless of variability in pharmacy generic acquisition costs. Furthermore, for brand prescriptions where a generic equivalent is available, Wisconsin Medicaid will only pay the generic price for the brand unless the physician

submits documentation to justify use of the brand. These policies are designed to encourage pharmacies to take advantage of all legally permitted generic substitutions.

The Wisconsin Medicaid program has established low MAC pricing on generics as a matter of policy for many years. Commission members who are practicing pharmacists reported that Wisconsin Medicaid's MAC prices are consistently the lowest in the market and sometimes fall below the drug's acquisition cost. These members said that not every pharmacy may be in a position to acquire generic drugs below the MAC prices set by Medicaid. This can be due to pre-established distribution channels and arrangements that do not allow acquisition at the lowest price of every drug in every instance. Commission members also reported, in addition to low MAC levels, Wisconsin Medicaid has more generic products subject to a MAC price than other Medicaid programs and other payers.

To document pharmacists' concerns about Wisconsin Medicaid's low MAC reimbursement rate policies, the Pharmacy Society of Wisconsin (PSW) submitted a study it had previously conducted that compares Wisconsin's generic pricing to other Medicaid programs. PSW compared Wisconsin Medicaid MAC rates for twenty commonly dispensed generic drugs to the MAC rates of seven other state Medicaid programs and found that Wisconsin's rates were 70% less than the other states' programs. See Appendix 4.

Brand Name Drug Ingredient Reimbursement

Wisconsin Medicaid reimburses pharmacies for brand name drugs (drugs still on patent) using a discount from Average Wholesale Price (AWP). AWP is a reference "price" for a single drug/dose combination that correlates with, but does not represent, the actual wholesale cost of the product. There is a single AWP for each drug that is accepted and used by payers for payment calculations. This information is systematically available to payers through companies such as First Data Bank.

Currently, Wisconsin Medicaid employs a payment formula for brand name drugs of AWP minus 13%. For SeniorCare, Wisconsin reimburses pharmacies at AWP-13% with a 5% premium, resulting in a net payment of AWP-8%. This formula also applies to generic drug products that are not yet on the MAC list. Products that have recently become available in generic form are "single source generics," made by only one generic manufacturer. In these cases, MAC pricing is not applied because pharmacies must pay a generic acquisition cost that more closely resembles a brand price.

Cost of Dispensing

The dispensing fee is an amount paid to the pharmacy as reimbursement for costs associated with providing the medication to the patient and all costs associated with being open as a business, including but not limited to: rent, utilities, staff salaries, equipment, compounding, patient counseling, and pharmacist time spent coordinating coverage information for the patient.

Wisconsin Medicaid's dispensing fee is currently \$4.38, both for brand and generic prescriptions. Providers are also allowed to bill \$0.015 per unit (pill) as an additional fee when medications are specially packaged as needed for effective utilization by a recipient.

David Kreling, Ph.D. of the University of Wisconsin-Madison, presented his research findings on the cost of dispensing among Wisconsin pharmacies and testified that, on average, it will cost Wisconsin pharmacies approximately \$9.50 to fill a prescription in 2006, and he estimated the cost in 2007 will be \$9.94. The slides from Dr. Kreling's presentation are attached in Appendix 5. Commission members pointed out that Dr. Kreling's model did not necessarily include additional costs that might be associated with serving Medicaid, BadgerCare or SeniorCare clients; specifically the costs of resolving prior authorization issues when consumers arrive with prescriptions for non-preferred drugs from the Medicaid preferred drug list. In addition, pharmacies generally do not incur costs of handling "coordination of benefits" with other payers as they do with Medicaid.

VII Reimbursement Recommendations

A subcommittee of the Commission developed and proposed a paper outlining fair reimbursement principles and describing a reimbursement methodology and formula that it believes meets these objectives. This proposal follows. The principles in the proposal received support from the majority of the Commission.

Wisconsin Pharmacy Reimbursement Commission
Establishing a Fair Pharmacy Reimbursement Formula for Wisconsin
Medicaid

Gary Donaldson, Commissioner
Kim Hodgkinson, Commissioner

The Wisconsin Pharmacy Reimbursement Commission has received testimony that clearly illustrates reimbursement problems facing pharmacies that participate in the Wisconsin Medicaid, SeniorCare, BadgerCare and HIRSP prescription drug programs. In order to maintain the quality and continuity of care currently enjoyed by these programs and their enrollees, system changes must be implemented that provide participating pharmacies with fair and equitable reimbursement for the prescriptions dispensed and services provided.

As two members of the Commission, we were tasked with the responsibility of making recommendations for revising the pharmacy reimbursement formula. It was our objective to recommend changes that were both an improvement to the current reimbursement formula as well as achievable within the budgetary constraints of the program. We recognize that additional policy decisions may need to be implemented in order to generate program savings to facilitate the increased payments associated with the reimbursement formula changes that we recommend.

Background

Multi-Source Generics and Application of State Maximum Allowable Costs (MACs)

Generic drugs provided by pharmacies to Medicaid recipients are reimbursed according to a state-based Maximum Allowable Cost (MAC) list that is established unilaterally by the Wisconsin Department of Health and Family Services (DHFS). This list was initially based upon the federal upper limits (FULs) established by the U.S. Department of Health and Human Services, Health Care Financing Administration (HCFA). HCFA based its published FUL list on a survey of generic drug prices available from national wholesalers.

In creating the Wisconsin MAC list, DHFS modified the FUL list to include additional drugs and lower prices based upon information obtained by DHFS about the price of generic drugs. The MAC allowances established by DHFS are substantially less than any other state Medicaid program as well as known commercial insurance programs.

The United States Congress has recommended changes to the Medicaid reimbursement policies for multi-source, generic drugs. If the differences in the current federal budget bills are reconciled between the U. S. House of

Representatives and the U. S. Senate, which they are expected to be, beginning on January 1, 2007 the new FUL will be based upon 250% of the average manufacturers price (AMP). It is not evident what the impact of this change will be to Wisconsin's programs, however, it will likely provide a new standard that will be used by Medicaid programs as the basis for reimbursement of multi-source drugs.

Brand Name, Single-Source Drugs

The current formula for single source, brand name drugs with FDA-granted market exclusivity and for innovator multiple source drugs with restrictive prescription status is the Average Wholesale Price (AWP) minus 13%. The discount off AWP has been increased from 10 percent to 13 percent over the past ten years. The new, lower rate proposed in the current state budget (based upon gubernatorial veto) would further increase the discount from AWP required of pharmacies, from AWP-13% to AWP-16%.

The Commission received reports and testimony regarding pharmacy acquisition costs of brand name drugs. Acquisition costs reported to the Commission ranged from AWP-17% to AWP-22%. However, pharmacy providers and some Pharmacy Commission members challenged the likelihood of many pharmacy providers acquiring all brand name drugs at the lowest end of that range.

Average Cost of Dispensing and Wisconsin Program Dispensing Fees

Wisconsin pharmacies currently recover less than half of their costs associated with dispensing a prescription through the dispensing fee. The current State budget calls for further reducing the dispensing fee, associated with the dispensing of both brand name and generic drugs, by fifty cents per prescription to \$3.88.

The Commission received reports that consistently illustrated that the average cost associated with the dispensing of a prescription drug by a pharmacy to be \$9.50 – \$10.00 per prescription. These costs correlate with testimony from individual pharmacist members of the Commission.

It is also important to recognize that the cost of dispensing studies are based upon averages, meaning that the operating costs of some pharmacies are more and others are less than the average. Using an average cost of dispensing methodology to establish reimbursement rates for pharmacy providers will cause all pharmacy providers to seek efficiencies in the dispensing process, especially those that have costs above the average.

The State also provides for an enhanced dispensing fee in limited circumstances. For example, increased payment is provided for the dispensing of compounded prescriptions and for providing pharmaceutical care services at the time of dispensing the prescription. Testimony provided by pharmacists who have used

the Pharmaceutical Care program indicated that the billing system for the enhanced services was in need of being updated and made more efficient.

In an effort to provide an innovative solution to the current pharmacy reimbursement problems facing the Wisconsin Medicaid, SeniorCare, BadgerCare and HIRSP programs, the Commission recommends that the State of Wisconsin implement the following measures:

1. Maintain current pharmacy reimbursement rates through the end of calendar year 2006.
2. Implement the cost saving policy initiatives outlined in Section III of the report.
3. Eliminate the 5% SeniorCare enhancement fee effective January 1, 2007.
4. Increase the AWP discount in the pharmacy reimbursement formula for brand name drugs to 15% effective January 1, 2007.
5. Maintain the current dispensing fee for brand name drugs.
6. Maintain the current process for establishing the generic MAC rates.
7. Increase the dispensing fee for generic drugs to \$9.88 effective January 1, 2007.
8. Implement the recommendations of the Commission for enhancing the Pharmaceutical Care program.

Rationale for Adopting the Commission's Pharmacy Reimbursement Recommendations

Commissioners voting in favor of the reimbursement recommendation submitted the following rationale in support of their position:

The current Wisconsin Medicaid reimbursement formula for generic drugs is: Wisconsin Medicaid MAC plus a \$4.38 dispensing fee. DHFS has stated numerous times that their MAC is at, or near, actual acquisition for pharmacies. So, if one compares the \$4.38 dispensing fee to the \$9.50 average cost to dispense from Dr. Kreling's study, it is obvious that the pharmacies are losing a significant amount of money when filling generic prescriptions for the Wisconsin Medicaid program. This is an unfair reimbursement formula and runs counter to the Governor's commitment of providing reimbursement levels that represent a fair price, and counter to the desire of DHFS to form a partnership with pharmacy providers.

For the generic reimbursement to be fair, it must cover the cost of the drug, and at the very least, the cost for the pharmacy to dispense the drug to the Medicaid recipient. The Commission established that Wisconsin MAC for generic drugs is at, or near, the cost of the drug. Therefore, the dispensing fee must be \$9.50 or above to achieve a fair level. The rationale for the \$9.88 dispensing fee is warranted and justified. For every prescription that is switched to a generic drug, the State saves a tremendous amount of money. The pharmacy should at the very least be able to break even on the transaction. If the pharmacy reimbursement recommendation is not adopted, the inadequacies in pharmacy payment by Wisconsin Medicaid for generic drugs will only increase as generic utilization increases.

To help offset the impact on the budget by increasing the generic dispensing fee, the Commission recommends increasing the discount off of AWP for brand name drugs from 13% to 15% and eliminating the 5% enhancement for SeniorCare. This accomplishes the goals of lowering expenditures on brand name drugs and requiring pharmacies to obtain drugs at very competitive prices. It also strengthens the incentive for pharmacies to switch patients from expensive brand name drugs to less expensive generic drugs.

Finally, when analyzing the budget impact of this recommendation, it should be considered in the context of the generic vs. brand drug trend which shows a marked increase in generic utilization over base.

This is the rationale for the Commission's recommendation and sound basis for the higher generic dispensing fee. The Commissioners understood this and a majority of them supported it by voting in favor of the recommendation.

VI Appendices

Appendix 1

DHFS Staff Analysis – Median Revenue Loss Resulting from Budget Veto

Appendix 2

Journal of the American Medical Association (JAMA) Sampling Editorial

Appendix 3

PSW Recommendations for the Commission

Appendix 4

Pharmacy Society of Wisconsin (PSW) Generics Comparison Spreadsheet

Appendix 5

Power Point Slides from Dr. Kreling's Presentation to the Commission

APPENDIX 1	
Governor's Pharmacy Reimbursement Commission	
Economic Impact of Proposed Rate Reduction	
Summary Statistics	
<i>Note: All amounts include claims from Medicaid, Badgercare and SeniorCare and all amounts are All Funds</i>	
Median Statistics	
Median Annual Paid by Pharmacy Provider (Adjusted for Part D)	\$194,244
Median Annual Medicaid Revenue Loss from Rate Reduction	\$6,983
Median Percent Revenue Loss	3.6%
Medicaid Revenue Loss from Rate Reduction, by Range	
<u>Range of Revenue Loss</u>	<u>Pharmacy Count</u>
Greater than \$100,000	7
\$50,000 to \$99,999	17
\$25,000 to \$49,999	94
\$15,000 to \$24,999	169
\$10,000 to \$14,999	191
\$5,000 to \$9,999	301
\$0 to \$4,999	501
Source: Division of Health Care Financing (12/13/05)	

Health Industry Practices That Create Conflicts of Interest

A Policy Proposal for Academic Medical Centers

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THE CURRENT INFLUENCE OF market incentives in the United States is posing extraordinary challenges to the principles of medical professionalism. Physicians' commitment to altruism, putting the interests of the patients first, scientific integrity, and an absence of bias in medical decision making now regularly come up against financial conflicts of interest. Arguably, the most challenging and extensive of these conflicts emanate from relationships between physicians and pharmaceutical companies and medical device manufacturers.¹

As part of the health care industry, pharmaceutical and medical device manufacturers promote the welfare of patients through their commitment to research and product development. Their investments in discovering, developing, and distributing new pharmaceutical agents and medical devices have benefited countless patients.

Conflicts of interest between physicians' commitment to patient care and the desire of pharmaceutical companies and their representatives to sell their products pose challenges to the principles of medical professionalism. These conflicts occur when physicians have motives or are in situations for which reasonable observers could conclude that the moral requirements of the physician's roles are or will be compromised. Although physician groups, the manufacturers, and the federal government have instituted self-regulation of marketing, research in the psychology and social science of gift receipt and giving indicates that current controls will not satisfactorily protect the interests of patients. More stringent regulation is necessary, including the elimination or modification of common practices related to small gifts, pharmaceutical samples, continuing medical education, funds for physician travel, speakers bureaus, ghostwriting, and consulting and research contracts. We propose a policy under which academic medical centers would take the lead in eliminating the conflicts of interest that still characterize the relationship between physicians and the health care industry.

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Most companies also support continuing medical education (CME). However, their ultimate fiduciary responsibility is to their shareholders who expect reasonable returns on their investments. Indeed, manufacturers are acutely aware of the conflict between patient vulnerability and profit incentives.

Recent congressional investigations, federal prosecutions, and class action lawsuits have brought to light documents demonstrating how company practices frequently cross the line between patient welfare and profit-seeking behavior.²⁻⁴ Concerned physicians, journalists, and federal prosecutors are exposing still other as-

pects of an unhealthy relationship between manufacturers and the medical profession.⁵⁻⁷

These transgressions have prompted pharmaceutical firms to regulate themselves more stringently. That effort is

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commendable, but physicians' behavior is a large part of the problem and industry efforts to date have not resolved the crisis. The standing of the profession, as much as the integrity of the pharmaceutical and medical device industries, is jeopardized by allowing obvious conflicts to continue.

The serious threat that this state of affairs poses for professionalism, and for the trust that patients have in physicians, makes the need for effective guidelines on industry-physician relationships both apparent and urgent. Marketing and market values should not be allowed to undermine physicians' commitment to their patient's best interest or to scientific integrity.

To remedy the situation and prevent future compromises to professional integrity, academic medical centers (AMCs) must more strongly regulate, and in some cases prohibit, many common practices that constitute conflicts of interest with drug and medical device companies. The guidelines we suggest are designed to promote broader professional self-regulation.

Why AMCs?

Academic medical centers, which include medical schools and their affiliated hospitals, should provide leadership for medicine in the United States. Just as pharmaceutical manufacturers look to AMCs for influential advice and support, so does the medical profession. Academic medical centers also have a major responsibility for training medical students and house staff. Research reveals that the habits learned or acquired during training persist into practice.⁸ Objectivity and scientific integrity should be central tenets of physician training.

Academic medical centers are also in a position to take immediate action. They are sufficiently well organized to gain commitments to a set of new principles in relatively short time. Moreover, independent research into the impact of medications and devices on population health is concentrated

in AMCs; therefore, unwarranted influence by manufacturers must be avoided. For these reasons, academic medicine should take the leadership in reforms, and other physicians and medical institutions should adopt their standards.

Defining Conflicts of Interest With Industry

Conflicts of interest occur when physicians have motives or are in situations for which reasonable observers could conclude that the moral requirements of the physician's roles are or will be compromised. In terms of industry influences, financial conflicts of interest occur when physicians are tempted to deviate or do deviate from their professional obligations for economic or other personal gain.⁹ The bias thus introduced violates both the best interests of patients and the standards of scientific integrity. Policing such conflicts clearly lies within the scope of professional responsibilities set forth in the *Physician Charter on Medical Professionalism*.^{10,11}

Traditionally, marketing by pharmaceutical and device companies has centered on company representatives or "detail persons" who visit individual physicians and provide information on new products. This practice has increased in scale and many other marketing strategies are also used. Approximately 90% of the \$21 billion marketing budget of the pharmaceutical industry continues to be directed at physicians, despite a dramatic increase in direct-to-consumer advertising.¹² In 2000, for example, the industry sponsored 314 000 events specifically for physicians.¹³ Moreover, industry contracted with many hundreds of physicians to serve on advisory boards or speakers' bureaus.⁵ The purpose behind such industry contacts with physicians is unmistakable: drug companies are attempting to promote the use of their products.

The following list, while not exhaustive, indicates the interactions with industry that must be addressed¹⁴: gifts, even of relatively small items, includ-

ing meals; payment for attendance at lectures and conferences, including on-line activities; CME for which physicians pay no fee; payment for time while attending meetings; payment for travel to meetings or scholarships to attend meetings; payment for participation in speakers' bureaus; the provision of ghostwriting services; provision of pharmaceutical samples; grants for research projects; and payment for consulting relationships.

These interactions have been examined by a variety of physician and industry groups, including the American Medical Association, the American College of Physicians, the Accreditation Council for Continuing Medical Education (ACCME), and the Pharmaceutical Research and Manufacturers of America.² The Office of the Inspector General of the Department of Health and Human Services has also released guidelines endorsing the Pharmaceutical Research and Manufacturers of America code.

In our view, the guidelines produced by these various groups and organizations are not sufficiently stringent and do not adequately uphold a professional commitment to patient welfare and research integrity. None of these groups establishes monitoring mechanisms or pinpoints responsibility for compliance. The profession itself must exert much tighter control over the relationships between manufacturers and physicians.

Myths of the Small Gifts and Full Disclosures

Most of the recommendations from medical and industry groups share 2 key assumptions. The first is that small gifts do not significantly influence physician behavior. The second is that disclosure of financial conflicts is sufficient to satisfy the need to protect patients' interests. Although these 2 assumptions are widely accepted among physicians, compelling research findings using a variety of methods have called their validity into question.

Psychologists, sociologists, and economists have explored human be-

havior in a conflicted situation using innovative experimental techniques.¹⁵ Their research has established that behavior is not entirely rational, individuals are not always conscious of their motives, and many popular beliefs about how individuals act in light of specific information are simply wrong.¹⁶

Social science research demonstrates that the impulse to reciprocate for even small gifts is a powerful influence on people's behavior. Individuals receiving gifts are often unable to remain objective; they reweigh information and choices in light of the gift.¹⁷ So too, those people who give or accept gifts with no explicit "strings attached" still carry an expectation of some kind of reciprocity.¹⁷ Indeed, researchers suggest that the expectation of reciprocity may be the primary motive for gift-giving.¹⁵

Researchers have specifically studied industry gifts to physicians. Receiving gifts is associated with positive physician attitudes toward pharmaceutical representatives.^{18,19} Physicians who request additions to hospital drug formularies are far more likely to have accepted free meals or travel funds from drug manufacturers.²⁰ The rate of drug prescriptions by physicians increases substantially after they see sales representatives,²¹ attend company-supported symposia,²² or accept samples.^{23,24} The systematic review of the medical literature on gifting by Wazana²⁵ found that an overwhelming majority of interactions had negative results on clinical care.

The assumption that disclosure to patients is sufficient to resolve problems created by physicians' conflicts of interest is also unfounded. First, physicians differ in what they consider to be a conflict, which makes the disclosure of conflicts incomplete. Because declarations of conflict are usually unverified, their accuracy is uncertain. Second, recipients of information who are not experts in a particular field often find it impossible to identify a biased opinion that they read or hear about that subject.¹⁷ Third, disclosure may be used to "sanitize" a problematic situa-

tion, suggesting that no ill effects will follow from the disclosed relationship.²⁶ Rather than eliminate the conflict, it is easier to disclose it and then proceed as though it did not exist.⁵

More Stringent Regulation

Because gifts of even minimal value carry influence and because disclosure is an inadequate safeguard, the guidance presently provided by the medical profession, the pharmaceutical industry, and the federal government fails to protect the best interests of patients and the integrity of physician decision making. For these reasons, many current practices should be prohibited and others should be more strictly regulated to eliminate potential sources of unwarranted influence.

Gifting. All gifts (zero dollar limit), free meals, payment for time for travel to or time at meetings, and payment for participation in online CME from drug and medical device companies to physicians should be prohibited. A complete ban on these activities by eliminating potential gray areas greatly eases the burden of compliance. It also frees physicians from deciding whether a gift is appropriate and removes a principal mode by which detail persons gain access to physicians' offices and influence their decision making.

Pharmaceutical Samples. The direct provision of pharmaceutical samples to physicians should be prohibited and replaced by a system of vouchers for low-income patients or other arrangements that distance the company and its products from the physician. The availability of free samples is a powerful inducement for physicians and patients to rely on medications that are expensive but not more effective. Samples also provide company representatives with access to physicians. The increasing reliance on direct-to-consumer advertising by drug companies only heightens the tension between current marketing practices and good patient care.

Drug companies believe that the interactions between sales representatives and physicians serve several pur-

poses, which include introduction of physicians to new medications, encouragement to use the most effective medications, improvement of the likelihood that they will follow good practice guidelines, and access to medications for low-income patients. From the perspective of medical professionalism, however, far better methods for securing these goals exist, all of which would be free of the pitfalls of marketing strategies.

Drug Formularies. Hospital and medical group formulary committees and committees overseeing purchases of medical devices should exclude physicians (and all health care professionals) with financial relationships with drug manufacturers, including those who receive any gift, inducement, grant, or contract. These policies would help ensure that decision making for formulary drugs and medical devices is based solely on the best available scientific evidence.

Continuing Medical Education. The widespread influence of drug manufacturers on current CME activities makes more stringent regulation necessary.²⁷ Manufacturers should not be permitted to provide support directly or indirectly through a subsidiary agency to any ACCME-accredited program. Manufacturers wishing to support education for medical students, residents, and/or practicing physicians should contribute to a central repository (eg, a designated office at an AMC), which, in turn, would disburse funds to ACCME-approved programs. This arrangement would permit the central repository and the ultimate recipients of funds to remain free from influence by any one donor company. To ensure accountability and to acknowledge generosity, the amount of funds contributed and the eventual use of the funds should be posted on a publicly available Web site.

This policy would likely reduce the contributions made by drug and device companies to CME programs. Companies acknowledge that they carefully evaluate the market impact of expenditures and support only

those demonstrating an increased use of their products.²⁸ Other ways of funding CME programs will have to be identified.

Funds for Physician Travel. Pharmaceutical and device manufacturers interested in having faculty or fellows attend meetings should provide grants to a central office at the AMC. That office could then disburse funds to faculty and training program directors. Trainees would no longer be directly dependent on industry largesse for educational opportunities.

Speakers Bureaus and Ghostwriting. Faculty at AMCs should not serve as members of speakers' bureaus for pharmaceutical or device manufacturers. Speakers bureaus are an extension of manufacturers' marketing apparatus. Because AMC faculty have a central role in the training of new physicians and represent their own institution, they should not function as paid marketers or spokespersons for medicine-related industries. By adhering to this recommendation, academic leaders will be upholding the principle that faculty opinion should be data driven and not for hire. For these same reasons, faculty should be prohibited from publishing articles and editorials that are ghostwritten by industry employees.

Consulting and Research Contracts. Because the process of discovery and development of new drugs and devices often depends on input from academic medicine, consulting with or accepting research support from industry should not be prohibited. However, to ensure scientific integrity, far greater transparency and more open communication are necessary. Accordingly, consulting or honoraria for speaking should always take place with an explicit contract with specific deliverables, and the deliverables should be restricted to scientific issues, not marketing efforts. So-called "no strings attached" grants or gifts to individual researchers should be prohibited. A contract with no identified deliverables is tantamount to a gift and should be regarded as such.²⁹

To promote scientific progress, AMCs should be able to accept grants for general support of research (no specific deliverable products) from pharmaceutical and device companies, provided that the grants are not designated for use by specific individuals. As long as the institution stands between the individual investigator and the company making the grant, the likelihood of undue influence is minimized but certainly not eliminated.

To better ensure independence, scientific integrity, and full transparency, consulting agreements and unconditional grants should be posted on a publicly available Internet site, ideally at the academic institution. This is important because company-funded research is more likely to produce positive results and on occasion companies have restricted the dissemination of research results unfavorable to their products.³⁰

One might argue that such an approach simply transfers the pressure surrounding financial conflicts to the institution and, as in the case of Oliveri at the University of Toronto, institutions have given in to pressure from pharmaceutical firms.³¹ But the requirements of public access and peer pressure will more effectively operate at the institutional level and such a policy is preferable to banning all contact between manufacturers and academic centers.

Going Forward

The benefits of such policies may convince the leadership of AMCs and medical schools to adopt them. We realize that some AMCs will be concerned that voluntarily adopting more stringent regulations may put them at a competitive disadvantage compared with those that do not.³² However, we hope their leadership will recognize that we call for changes in current AMC practices that are, in many respects, modest. For example, existing guidelines prohibit all gifts from industry except those that are small; going one step further and eliminating token gifts should not cause great disruption and may bring greater clar-

ity. Grants and consulting are not prohibited but must be transparent and subject to peer review. Although such steps may cause significant challenges for medical schools and affiliated institutions, students, physicians, and the public deserve unbiased medical education, research, and clinical care.

Industry has good reason to accommodate itself to these policies and will continue to seek assistance from academic consultants and researchers. Commercial entities working with AMCs cannot be pleased about the diminished respect and growing public mistrust of their activities in the current environment.

Medical schools must be prepared to monitor compliance and enforce the rules we have outlined. There will be costs associated with oversight and perhaps a decline of collegiality among faculty. But these negative aspects will depend to some extent on the prevalence of violations. If AMC leaders educate colleagues and build a consensus around these principles, compliance will follow.

What then might the world of medicine look like if these proposals are widely adopted? First, decisions by physicians on which prescription to write and which device to use might become more evidence-based; medical societies' practice guidelines might become less subject to bias. A greater reliance on objective sources for accurate and up-to-date information would also promote better patient outcomes. Second, total expenditures on prescription drugs might decline. An increased use of generic products, increased use of comparable but less expensive patent-protected products, and, in some cases, a decreased reliance on pharmaceutical agents might be observed. Third, although AMCs and professional societies would have to find alternative sources for funding programs, the absence of industry representatives at AMC meetings and lunches and in corridors would increase the sensitivity among medical students and house staff to the values of medical professionalism and scientific integrity.

Rules would be standardized, not, as now, with some departments prohibiting drug company lunches, others allowing them; some hospitals permitting the sales representatives to see their physicians, others not. Medical society meetings would also assume a more professional tone and the substance

of the programs would become more scientific.

Ultimately, the implementation of these proposals will substantially reduce the need for external regulation to safeguard against market-driven conflicts of interest, and the medical profession will reaffirm very publicly its

commitment to put the interests of patients first.

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Appendix 3

Pharmacy Society of Wisconsin's Recommendations for the Commission

Chris Decker, RPh, Executive Director, Pharmacy Society of Wisconsin (PSW), reiterated that the Commission's charge is to find savings and to ensure fair payments to pharmacists.

As such, PSW recommends the following:

- € Increase Wisconsin Medicaid dispensing fee to the average cost of dispensing in Wisconsin.
- € Adopt an enhanced dispensing fee for generics
 - \$12 dispensing fee for generics; \$8 dispensing fee for brands – given that the average cost to dispense is \$10 per script.
- € Simplify Pharmaceutical Care.
- € Develop a statewide standard on medication management with the State taking a leadership role.
- € Account for the full impact of blockbuster drugs going generic over the next biennium.
- € Reform the Brand Medically Necessary prior authorization approval system.
- € Require greater prescriber responsibility for prior authorization.
- € Adopt additional incentives for generics, e.g., a pill-splitting program, an expanded Medication Therapy Management program.
- € Ensure that the State is collecting all rebate dollars that it is entitled to collect.
- € Work with providers to ensure that the most cost-effective product is used.

Appendix 4 (Provided by PSW) State MAC Comparison of 20 Top Generic Drugs

Generic Drug Product Description	Innovator	Form	ST	WI	LA	VA	MN	NE	MO	IN	IL	Qty	WI Total \$	IA Total \$	VA Total \$	MN Total \$	NE Total \$	MO Total \$	IN Total \$	IL Total \$
Furosemide	Lasix	Tab	40	\$0.05	\$0.06	\$0.05	\$0.06	\$0.06	\$0.06	\$0.04	\$0.04	15,431.917	\$771,595.84	\$924,371.82	\$771,595.84	\$925,195.01	\$924,371.82	\$924,371.82	\$617,276.67	\$592,585.61
Ranitidine	Zantac	Tab	150	\$0.04	\$0.34	\$0.23	\$0.14	\$0.08	\$0.09	\$0.06	\$0.06	13,396,560	\$535,862.41	\$4,569,566.70	\$3,031,641.58	\$1,913,028.80	\$1,071,724.82	\$1,227,124.92	\$781,019.46	\$3,483,105.67
Furosemide	Lasix	Tab	20	\$0.04	\$0.06	\$0.05	\$0.06	\$0.04	\$0.05	\$0.04	\$0.06	12,983,699	\$519,347.96	\$730,982.25	\$633,604.51	\$730,982.25	\$454,429.47	\$623,217.55	\$454,429.47	\$779,021.94
Ranitidine	Zantac	Gel	150	\$0.04	\$0.15	\$0.23	\$0.52	\$0.08	\$0.41	\$0.41	\$0.26	12,539,525	\$501,581.01	\$1,880,928.79	\$2,884,090.81	\$6,335,600.56	\$1,003,162.02	\$5,148,729.07	\$5,124,903.97	\$3,260,276.57
Acetaminophen; Hydrocodone	Vicodin	Tab	500/5	\$0.09	\$0.08	\$0.10	\$0.12	\$0.08	\$0.07	\$0.05	\$0.04	10,966,557	\$936,283.78	\$913,514.21	\$1,096,653.71	\$1,315,986.85	\$877,324.57	\$740,242.60	\$548,327.86	\$462,788.71
Ciprofloxacin	Cipro	Tab	500	\$0.12	\$0.60	\$0.33	\$0.20	\$0.20	\$0.38	\$0.16	\$0.15	8,060,867	\$967,304.04	\$4,836,520.20	\$2,660,086.11	\$1,612,173.40	\$1,612,173.40	\$3,059,905.11	\$1,274,423.07	\$1,184,947.45
Acetaminophen; Propoxyphene	Darvocet	Tab	650/100	\$0.11	\$0.18	\$0.12	\$0.08	\$0.10	\$0.15	\$0.12	\$0.07	4,966,567	\$546,322.42	\$893,982.14	\$593,988.09	\$397,325.40	\$496,656.75	\$751,938.31	\$595,988.09	\$339,713.21
Potassium Chloride ER	Micro K	Cap	10	\$0.14	\$0.22	\$0.19	\$0.14	\$0.18	\$0.23	\$0.19	\$0.16	4,704,917	\$638,688.42	\$1,020,967.05	\$893,934.28	\$635,163.83	\$846,885.11	\$1,066,604.75	\$915,106.41	\$752,786.77
Metformin	Glucophage	Tab	500	\$0.13	\$0.36	\$0.31	\$0.36	\$0.15	\$0.15	\$0.12	\$0.11	4,387,077	\$570,320.05	\$1,560,483.40	\$1,348,387.56	\$1,360,483.40	\$636,126.21	\$679,119.57	\$511,094.51	\$493,107.49
Omeprazole Delay Released	Prilosec	Cap	20	\$1.80	\$3.29	\$2.92	\$2.54	\$1.67	\$2.79	\$2.49	\$2.70	3,819,900	\$6,875,819.70	\$12,578,166.17	\$11,146,467.71	\$9,702,545.58	\$6,379,232.72	\$10,664,014.36	\$9,521,864.31	\$10,313,729.55
Albuterol Sulfate	Proventil	Soln	90mcg	\$0.35	\$0.74	\$0.49	\$0.88	\$0.59	\$0.39	\$0.27	\$0.26	2,695,527	\$943,434.31	\$2,007,089.11	\$1,308,139.06	\$2,378,263.12	\$1,590,360.69	\$1,053,681.35	\$727,522.63	\$694,906.76
Potassium Chloride SR	K-Dur	Tab	20 meq	\$0.22	\$0.52	\$0.34	\$0.21	\$0.29	\$0.38	\$0.24	\$0.24	2,490,869	\$547,991.13	\$1,295,251.76	\$844,653.60	\$523,082.44	\$729,077.29	\$949,519.18	\$591,332.25	\$588,592.29
Loratadine	Claritin	Tab	10	\$0.30	\$0.38	\$0.33	\$0.70	\$0.47	\$0.40	\$0.54	\$0.46	2,250,611	\$675,183.44	\$855,232.36	\$742,701.78	\$1,575,428.03	\$1,057,787.39	\$891,467.20	\$1,210,828.97	\$1,035,281.27
Baclofen	Lioresal	Tab	10	\$0.25	\$0.45	\$0.33	\$0.45	\$0.24	\$0.38	\$0.19	\$0.45	2,054,759	\$513,689.81	\$922,997.85	\$677,043.17	\$922,997.85	\$493,142.22	\$777,520.90	\$395,541.15	\$924,641.66
Tizanidine	Zanaflex	Tab	4	\$0.36	\$0.65	\$0.87	\$0.65	\$1.05	\$0.59	\$0.41	\$0.43	1,736,359	\$625,089.31	\$1,128,459.84	\$1,510,111.59	\$1,128,459.84	\$1,823,177.15	\$1,020,979.21	\$713,122.72	\$746,634.45
Clozapine	Clozaril	Tab	100	\$1.50	\$2.68	\$2.70	\$1.36	\$1.80	\$1.60	\$1.27	\$1.25	1,273,811	\$1,910,716.78	\$3,415,724.70	\$3,444,894.97	\$1,727,924.87	\$2,292,860.14	\$2,033,639.56	\$1,614,173.54	\$1,586,022.31
Paroxetine HCL	Paxil	Tab	20	\$1.20	\$2.52	\$2.28	\$2.54	\$1.30	\$2.08	\$1.82	\$1.60	1,232,977	\$1,479,571.97	\$3,107,101.14	\$2,807,487.81	\$3,135,610.13	\$1,602,869.63	\$2,561,508.97	\$2,245,003.87	\$1,968,817.10
Mirtazapine	Remeron	Tab	15	\$0.45	\$1.63	\$1.20	\$0.38	\$0.33	\$1.37	\$2.02	\$1.09	1,225,551	\$551,497.90	\$1,997,647.95	\$1,464,900.98	\$460,807.13	\$404,431.79	\$1,681,946.04	\$2,479,412.00	\$1,335,850.47
Paroxetine HCL	Paxil	Tab	40	\$1.30	\$2.17	\$2.53	\$2.73	\$1.40	\$2.30	\$2.04	\$1.74	590,956	\$768,243.13	\$1,282,611.45	\$1,495,769.37	\$1,614,728.87	\$827,338.76	\$1,358,903.91	\$1,207,500.91	\$1,030,332.23
Paroxetine HCL	Paxil	Tab	30	\$1.20	\$2.07	\$2.40	\$2.67	\$1.30	\$2.20	\$1.90	\$1.20	528,500	\$634,199.76	\$1,091,827.74	\$1,266,179.82	\$1,410,037.47	\$687,049.74	\$1,162,435.31	\$1,005,735.12	\$634,199.76
Grand Total													\$21,552,743.17	\$47,013,426.62	\$40,624,534.38	\$40,204,544.84	\$25,810,181.68	\$38,376,869.68	\$32,534,606.99	\$32,207,341.26

This report was prepared by the Pharmacy Society of Wisconsin through a comparison and analysis of generic drug reimbursement levels of several state Medicaid programs in the Midwest. A national comparison was not possible due to the lack of availability of data. Michigan would not provide its Medicaid MAC reimbursement levels, claiming the information proprietary.

The report represents 20 of the most commonly used generic medications in Wisconsin Medicaid that account for more than one million prescriptions annually and approximately 20% of the total number of generic prescriptions dispensed to Wisconsin Medicaid recipients.

The quantity referenced on the spreadsheet is the number of units (tablets, capsules etc.) dispensed to Wisconsin Medicaid recipients over the last fiscal year. Each state's MAC price, per unit, was multiplied by the number of units used by Wisconsin Medicaid in order to create a relative comparison of the reimbursement amount, for each state, for the same number of units used in Wisconsin Medicaid.

HP04024/PERM

Appendix 5

Pharmacy Cost Parameters: Dispensing and Drug Acquisition Costs

David H. Kreling, Ph.D.
Sonderegger Research Center
School of Pharmacy
University of Wisconsin - Madison

DHFS Pharmacy Reimbursement Commission Meeting

15 December 2005

HP04024/PERM

Goals:

1. Highlight DHFS 2002 study findings
2. Update cost estimates
3. Provide other marketplace parameters and insights

1. DHFS Study Topic & Goals

Cost of dispensing - what is the average cost of dispensing a prescription among pharmacies in Wisconsin?

Acquisition cost - how do purchase costs of pharmaceuticals relate to reference prices (i.e., actual acquisition cost (AAC) vs. average wholesale price (AWP) - percent “discount”

Results intended to inform rate setting for pharmacy payment/reimbursement in Medicaid program.

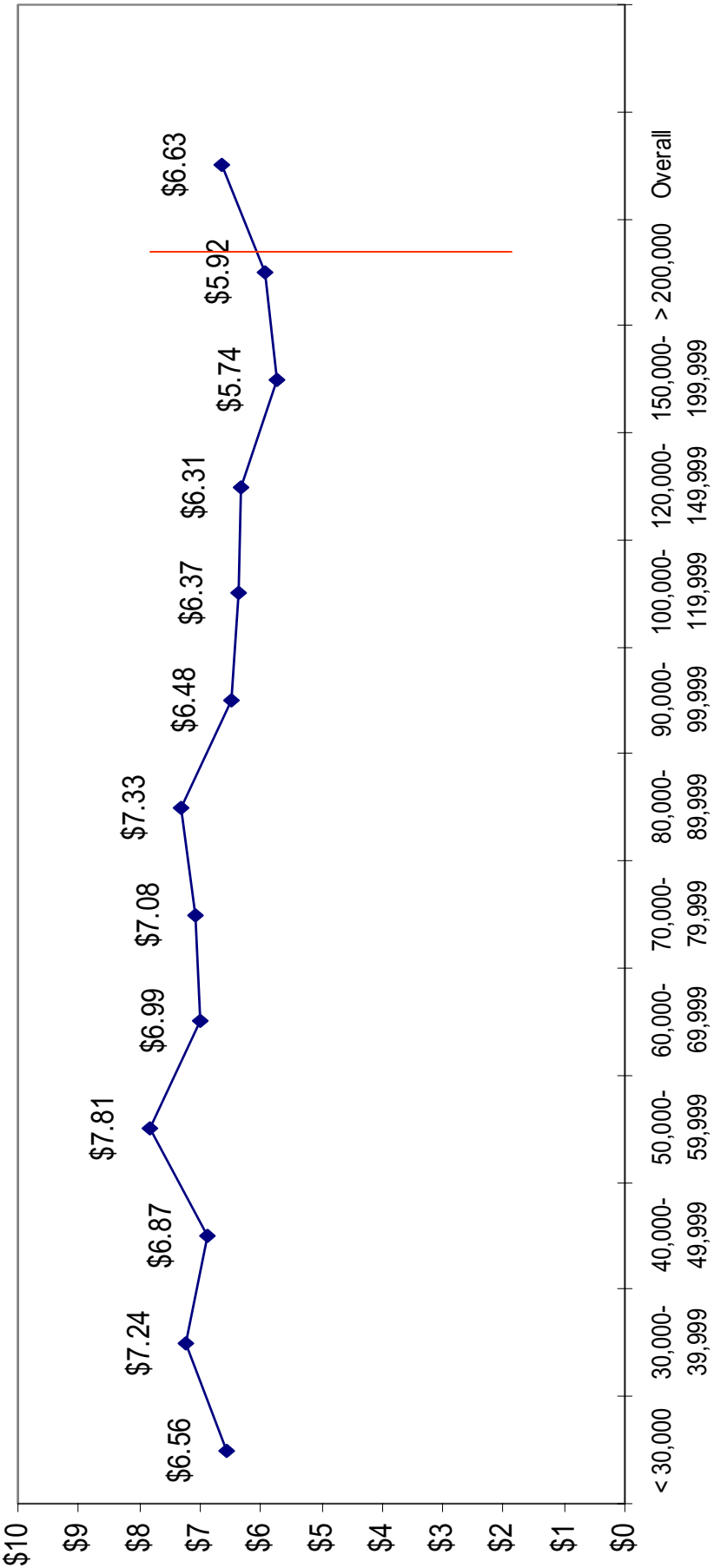
DHFS Cost of Dispensing Study Findings

Overall (N=185)	\$6.972
<5,>10 excluded (N=167)	\$6.846
<4.5,>10 excl (N=149)	\$6.627
Overall range = \$3.96 to \$17.49; std. dev. = \$2.07	

Calculations based on data from FY ending in 2000.

Results include independent, chain, and mass merchandiser pharmacies.

Cost of Dispensing by Prescription Volume



Excludes extreme values < \$4.50 and > \$10.00

HP04024/PERM

Updating DHFS Study Results

	<u>2000 Actual*</u>			<u>2005 Estimated</u>		
	Sal/RX	Oth/RX	Total	Sal/RX	Oth/RX	Total
All	3.983	3.025	7.008	5.587	3.389	8.976
Outliers1	3.780	2.859	6.638	5.301	3.203	8.504
Outliers2	3.859	3.004	6.863	5.413	3.365	8.778

Outliers 1 = <4.5,>10 excl.; Outliers2 = <5,>10 excl.

* Data points w/o salary detail excluded; N=6 excluded

Estimated using 7.0% per annum growth rate for salaries, 2.3% per annum for other expenses.
 7.0% per annum growth rate from 1999 - 2003 WI RPh Compensation Surveys;
 2.3% per annum growth rate is average annual growth in the CPI, all items, from the BLS

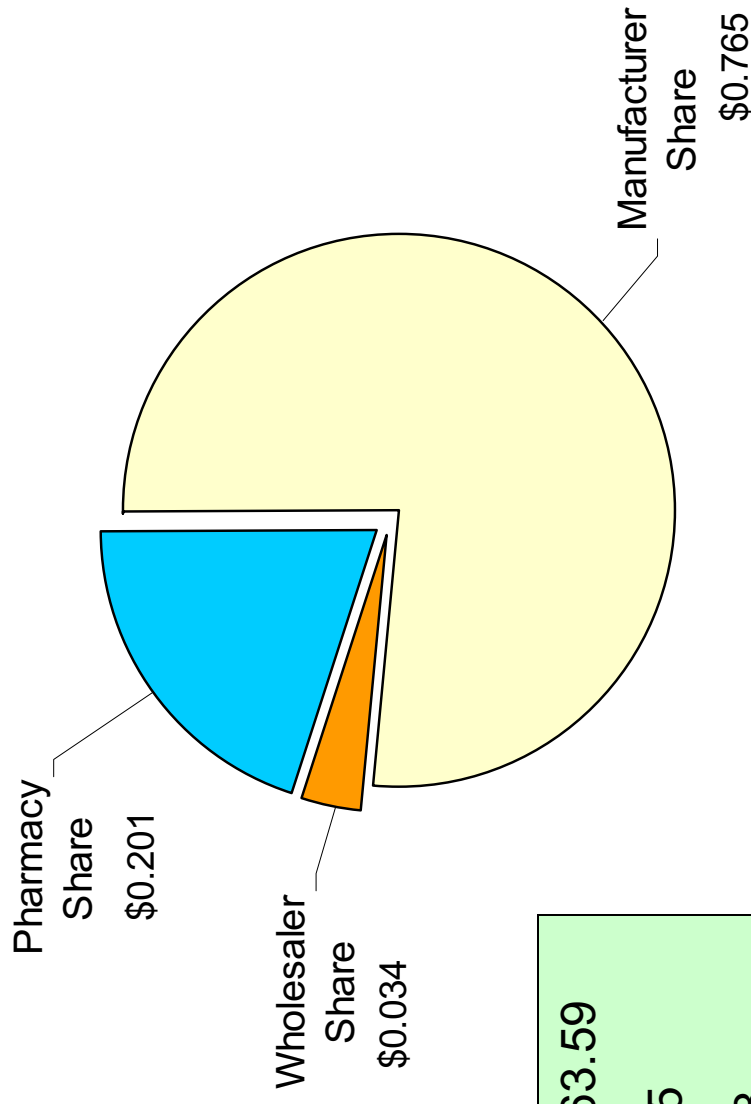
Updating DHFS Study Results

2005 Estimated			2006 Estimated			2007 Estimated		
Salary	Other	COD	Salary	Other	COD	Salary	Other	COD
\$5.59	\$3.39	\$8.98	\$5.98	\$3.47	\$9.45	\$6.40	\$3.55	\$9.94
\$5.41	\$3.37	\$8.78	\$5.79	\$3.44	\$9.23	\$6.20	\$3.52	\$9.72
\$5.30	\$3.20	\$8.50	\$5.67	\$3.28	\$8.95	\$6.07	\$3.35	\$9.42

Estimated using 7.0% per annum growth rate for salaries, 2.3% per annum for other expenses.
 7.0% per annum growth rate from 1999 - 2003 WI RPh Compensation Surveys;
 2.3% per annum growth rate is average annual growth in the CPI, all items, from the BLS

Other Marketplace Parameters

Distribution of a Dollar of Revenue from a Retail Prescription, 2004



Average RX Price = \$63.59

Manufacturer: \$48.65

Wholesaler: \$2.18

Pharmacy: \$12.77

Source: National Association of Chain Drug Stores, nacds.org, data for 2004

Extrapolating a Cost Estimate - National Marketplace Parameters

Average RX Price = \$63.59

Manufacturer: \$48.65

Wholesaler: \$2.18

Pharmacy: \$12.77

Gross Margin (\$12.77 = cost of dispensing + profit)

"Reasonable" profit (?) = 5%, then,

$\$63.59 * 0.05 = \3.18 (profit);

COD = GM less profit = $\$12.77 - \$3.18 = \$9.59$

DHFS Study Results: Drug Acquisition Costs

Type of Drug	Wholesaler 1 Avg. % Discount (Range)	Wholesaler 2 Avg. % Discount (Range)	Wholesaler 3 Avg. % Discount (Range)
Single-Source (Brand Name)	17.46% (14.57 - 26.18) N=199	17.54% (14.15 - 24.10) N=145	17.23% (12.50 - 23.67) N=169
Multiple-Source Innovator (Brand Name)	17.64% (14.99 - 26.07) N=94	17.71% (14.16 - 26.24) N=39	18.13% (12.48 - 32.41) N=82
Brand Name (SS & MSI Combined)	17.52% (14.57 - 26.18) N=293	17.58% (14.15 - 26.24) N=184	17.52% (12.48 - 32.41) N=251
Multiple-Source Generic	76.16% (22.60 - 98.79) N=192	75.34% (14.29 - 98.40) N=91	74.44% (10.97 - 98.21) N=154

Data for January 2001

Model values: Brand name @ 15-17%, and 19-20%; Multiple-source generics @ 70+%

Acquisition Cost Study Updates/Marketplace Parameters

AWP vs. AAC: Percent off AWP = AAC	
Brand Name (N=453):	21.31%
Range:	17.03 - 40.79
Std Dev.:	1.44%
Modal:	21.2 (11 < 21.1%; 6 > 22.5%)
Generic Name (N= 339):	77.24%
Range:	31.95 - 98.66
Std Dev.:	16.34%
Modal:	??

Calculations based on data accessed November 2005, from buying group website.

Estimating Proposed Changes - Impact

Formula changes from AWP less 13% to AWP less 16%.

Average Brand RX price = \$96.01

Less average margin (\$12.77)

Cost of drug dispensed = \$83.24

If AAC = AWP less 21%, then AWP = \$105.36

3% of AWP at \$105.36 AWP = \$3.16

= average amount of ingredient payment cost reduction

(Plus, \$1.00 for each dispensed prescription from dispensing fee reduction)

RELEVANT QUESTIONS

What are Medicaid prescription payment goals?

What is the role of accurate cost information?

How can the State ensure they are a prudent purchaser?

IDEAS

Establish accurate drug acquisition cost payment mechanism. Electronic funds transfer technology?

Establish accurate, cost-based dispensing fee.

Market based/ linked to market parameters?

Continue efforts for "big ticket" item savings opportunities.

Wisconsin Pharmacy Reimbursement Commission

Minority Report

Bruce Weiss, M.D., M.P.H., Commissioner

Douglas Lee, M.D., Commissioner

Patricia Finder-Stone, R.N., Commissioner

The Wisconsin Pharmacy Reimbursement Commission was appointed by the Governor to recommend changes to the State's pharmacy reimbursement system for the Medicaid, BadgerCare, SeniorCare and HIRSP programs to reduce costs while maintaining vital benefits. These recommendations could include implementing an alternative methodology for setting the acquisition price for name brand and generic drugs, using a tiered reimbursement system, and/or changes to the dispensing fee to reflect the level of therapeutic review.

As members of the Commission in the minority, we were asked to outline the few issues we differ from our colleagues. In general, we are in agreement with the Commission's recommendations regarding enhancement of the Pharmaceutical Care program, Preferred Drug List, supplemental drug rebates and increased generic utilization. While we support fair reimbursement for pharmacies, we do not agree with the reimbursement scenario adopted by the Commission majority.

Background

Medicaid, BadgerCare and SeniorCare pharmacy copayments are statutorily limited and are substantially less than those of commercial and Medicare. The lack of copayment differential between generic and brand drugs creates greater dependence on pharmacists' intervention and formulary management to promote appropriate generic utilization.

Current reimbursement methodology for generic drugs may actually be set too low and may discourage dispensing of generic medications. Ingredient payments for some generic drugs are reported to be at or below actual acquisition costs (AAC) for some pharmacies, due to aggressive maximum allowable cost (MAC) price management. At the same time, the proportion of generic drugs has been increasing due to the implementation of a preferred drug list (PDL) and more assertive management of Brand Medically Necessary (BMN) medications. These factors have created a worsening financial dilemma for pharmacies in that they are not being reimbursed their costs for a greater percentage of Medicaid prescriptions.

Conversely, Medicaid reimbursement for brand medications exceeds AAC and is greater than comparable commercial rates. Historically, the excessive Medicaid payments on branded drugs offset the marginal payments on generics. A more rational reimbursement strategy would increase generic reimbursement and lower reimbursement for brand drugs, thereby encouraging rather than discourage generic utilization.

Future reimbursement strategies need to reallocate cost savings from brand drugs to generic drugs. This can be done by: maintaining the current MAC pricing and increasing the generic dispensing fee; maintaining the current dispensing fee and increasing the MAC pricing; or a combination of the two.

Additional reimbursement strategies to streamline and increase reimbursement to pharmacies for services that result in savings to the State should also be implemented. This can be achieved by additional payments for specific services such as pill splitting, facilitating a switch from brand to generic, elimination of duplicative or unnecessary medication via the Pharmaceutical Care program, as well as, supporting the State's preferred drug list by coordinating prior authorizations.

Our positions are based on the following principles against which a proposed reimbursement formula can be tested:

- € Access to vulnerable patients should be assured.
- € Quality of the care being purchased should be maintained or enhanced.
- € The State of Wisconsin should be a prudent purchaser so that expenditures provide the maximum benefit to the citizens of the State.
- € Increased payments should be targeted towards payment for performance by rewarding pharmacies to promote greater generic use and to enhance patient care and lower overall costs.

If pharmacy payments are fair, and are targeted to appropriate actions as suggested in the Majority Report, then access and quality would be assured. The question is "what level of reimbursement is needed to be fair?"

The Commission heard testimony about potential withdrawal of service from pharmacists based on inability to stay in business. Anecdotal testimony was given that current reimbursement is inadequate for small pharmacies because they cannot purchase drugs as efficiently as larger entities. However, no documentation was presented or provided to substantiate this apparent variation in small pharmacy acquisition costs and to quantify how many pharmacies are impacted.

Although there was agreement that the average cost to a pharmacy to dispense a drug is about \$9.50, there is public information from chain pharmacies reporting costs in that setting as low as \$4.50 per prescription.

Evidence was presented that, on a statewide basis, pharmacies accept payment terms from commercial payers at or below Medicaid rates. Evidence was not presented that Medicaid overpays or underpays globally.

This leaves us with two problems:

- € In the absence of full data, it is not possible to make a recommendation for any specific reimbursement formula or level with confidence that money is being spent wisely.
- € Any reimbursement level that allows the least efficient critical access pharmacy to be profitable guarantees that the State will not be purchasing prudently elsewhere.

Although the majority report's payment formula recommendations in combination with the other cost containment measures recommended come very close to meeting the level of savings sought by the Governor in this biennium, the payment formula effectively negates much of the utilization savings in successive biennia.

Recommendations

1. We support the reduction of reimbursement for brand medications through a greater discount off of AWP to decrease the profit disparity between brand and generic drugs.
2. We support a modest increase in reimbursement for generic medications, either through an increase in dispensing fee or higher MAC prices to decrease the profit disparity between brand and generic drugs. However, we do not support raising the dispensing fee to the level recommended by the Commission majority (\$9.88).
3. We strongly support the remaining Commission recommendations regarding the Pharmaceutical Care program, prohibition of sampling, pill splitting, targeted brand to generic switching, mandatory generic and further expansion of the preferred drug list.
4. For those small independent pharmacies that believe that they are not being adequately reimbursed, we recommend that DHFS, in accordance with existing provisions, review the pharmacies' costs and their payment terms from other payers, in order to set appropriate reimbursement.